



UNITED STATES PATENT AND TRADEMARK OFFICE

*AA*

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 10/728,560      | 12/05/2003  | Alcandro DiGianfilippo | BBM-103US           | 9986             |

23122 7590 12/18/2006  
RATNERPRESTIA  
P O BOX 980  
VALLEY FORGE, PA 19482-0980

EXAMINER

CABRERA, ZOILA E

ART UNIT PAPER NUMBER

2125

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 12/18/2006 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

|                                      |   |  |
|--------------------------------------|---|--|
| <b>Application No.</b><br>10/728,560 | <b>Applicant(s)</b><br>DIGIANFILIPPO ET AL. |  |
| <b>Examiner</b><br>Zoila E. Cabrera  | <b>Art Unit</b><br>2125                     |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 05 October 2006.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-21 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) 1 and 7-19 is/are allowed.
- 6)  Claim(s) 2-6, 20-21 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5)  Notice of Informal Patent Application
- 6)  Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1-21 are presented for consideration.

#### *Response to Arguments*

2. Applicant's arguments with respect to claims 2-6 and 20-21 have been considered but are moot in view of the new ground(s) of rejection.

#### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4, 6 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kircher et al. (US 6,975,924) in view of de la Huerga (US 7,006,894).

Kircher discloses:

2. A compounding control method to prepare a compounded mixture for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle, the method comprising the steps of: a) determining whether said plurality of source solutions conform to a predetermined configuration (Fig. 4A, i.e. concentration within allowed range?; Col. 12, lines 37-Col. 13, line 5); b) **at least one of** providing an alert to an operator and preventing

Art Unit: 2125

compounding based on said determining step a) (Fig. 4A Display Alarm; Col. 14, line 57 to Col. 15, line 20; Col. 19, lines 1-4); e) accepting mixture inputs for one or more of said plurality of source solutions (Fig. 4A Input Prescription; Col. 8, lines 18-28); f) determining a nutritional assessment of a patient; g) comparing said mixture inputs with said nutritional assessment; and h) providing an output to a user based on said comparison (Col. 7, line 54 to Col.8, line 39); and i) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture (Col. 11, lines 1-13); .

As for claim 3, the same citations applied to claim 2 above apply as well for claim 3.

Kircher further discloses: determining if a lipid source solution and a dextrose source solution one of immediately follow or immediately precede one another; generating an alert to a user based on said determination; and preventing further processing of the compounded mixture until at least one buffer source solution is selected to be provided between said lipid source solution and said dextrose source solution (Col. 10, lines 53-57; Col. 9, lines 38-40; Col. 9, lines lines 65 to Col. 10 line 5).

As for claim 6, the same citations applied to claim 2 above apply as well for this claim.

Kircher further discloses selecting at least one of an infusion ramp-up time and a ramp-down time for dispensing the compounded mixture (Col. 12, line 54- Col. 13, line 5)

However Kircher does not disclose some limitations of claims 2, 20, 21 and the limitations of claims 4 and 7. But de la Huerga discloses such limitations as follows:

As for claim 2,

c) determining respective expiration dates of said plurality of source solutions (Col. 15, lines 4-16); d) at least one of providing a warning and preventing use of any of said plurality of source solutions based on said determination step c) (Col. 15, lines 18-21).

As for claims 4 and 7,

4. The method according to claim 1, further comprising the step of generating a bar coded label based at least in part on a composition of the compounded mixture in the mixture receptacle (Fig. 5, Col. 7, lines 9-11).

7. The method according to claim 1, wherein said determining step c) is based at least in part on a bar code scan of said source solution (Col. 13, lines 57-62; Col. 15, lines 4-21).

As for claims 20-21, the same citations applied to claims 2 and 5 above apply as well for these claims. As for claim 20, Kircher further discloses determining if a plurality of said compounded mixture are to be prepared; determining if any of a plurality of additive

Art Unit: 2125

solutions are to be part of said compounded mixture; determining if any of said plurality of additive solutions may be pooled into a pooled additive solution; urging at least one of said plurality of additive solutions into a pooled additive solution container; and designating said pooled additive solution as a further source solution for preparation of said compounded mixture (Col. 6, lines 24-35).

Therefore, it would have been obvious to a person of the ordinary skill in the art at the time the invention was made to combine the teachings of Kircher with the teachings of de la Huerga because it would provide an improved system wherein information about expired solutions or medication that exceeds shelf life can be easily identified and thereby an alarm or display may be activated when such an occurrence arises (Col. 6, lines 13-33).

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kircher et al. (US 6,975,924) and de la Huerga (US 7,006,894) and further in view of Martucci et al. (US 5,927,349).

Kircher and de la Huerga disclose the limitations of claim 2 above, the same citations applied to claim 2 above apply as well for claim 5 with the exception of selecting an infusion pump type for dispensing the compounded mixture prior to beginning compounding the compounded mixture. However, Martucci discloses selecting an infusion pump type for dispensing the compounded mixture prior to beginning compounding the compounded mixture (Col. 5, line 57 to Col. 6, line 3).

Art Unit: 2125

Therefore, it would have been obvious to a person of the ordinary skill in the art at the time the invention was made to combine the teachings of Kircher and de la Huerga with the compounding assembly of Martucci because it would provide an improved system wherein the solutions are prepared in a safe, efficient and accurate manner (Col. 1, lines 20-21).

***Allowable Subject Matter***

5. Claims 1 and 7-19 are allowed.

The following is an examiner's statement of reasons for allowance: The allowability of the claims resides, at least in part, that the prior art of record does not disclose or suggest, alone or in combination the step of:

As for independent claim 1, **scanning a bar code of said installed plurality of source solutions; scanning a bar code of respective ones of transfer tubing adapted to be coupled to said plurality of source solutions; comparing the scanned information of the installed plurality of source solutions and transfer tubing with an expected configuration; either permitting the operator to commence compounding if the comparison is valid or preventing the operator from compounding if the comparison is invalid**, in combination with the other elements and features of the claimed invention.

As for independent claim 11, **determining a state of motion of a plurality of pump elements of said compounding device; generating a first alert signal if any**

Art Unit: 2125

**of said plurality of pump elements are in a state of motion that should otherwise be stationary, said alert advising of a defective compounded mixture; and generating a second alert signal if any of said plurality of pump elements are in a stationary state that should otherwise be in motion, in combination with the other elements and features of the claimed invention.**

As for independent claim 16, **advising a user of at least one of maintenance procedures and replacement of component parts of the compounder device; receiving input from said user responsive to said advising step and preventing further processing of said compounded mixture until said input from said user indicates compliance with said advising step, in combination with the other elements and features of the claimed invention.**

As for independent claim 17, **providing the user with an inventory of mixture receptacles for selection; receiving an input from the user for selecting a desired mixture receptacle; comparing said selection with a volume of said desired compounded mixture based on said mixture inputs of step e); and generating an alert to said user if said volume of said desired compounded mixture exceeds a volume of said selected mixture receptacle and preventing further processing until an alternate selection of a mixture receptacle is made that will accommodate said compounded mixture, in combination with the other elements and features of the claimed invention.**



Art Unit: 2125

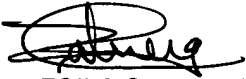
**Conclusion**

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning communication or earlier communication from the examiner should be directed to Zoila Cabrera, whose telephone number is (571) 272-3738. The examiner can normally be reached on M-F from 8:00 a.m. to 5:30 p.m. EST (every other Friday).

If attempts to reach the examiner by phone fail, the examiner's supervisor, Leo Picard, can be reached on (571) 272-3749. Additionally, the fax phones for Art Unit 2125 are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist at (703) 305-9600.

Zoila Cabrera  
Primary Examiner  
12/8/06

  
ZOILA CABRERA  
PRIMARY EXAMINER  
TECHNOLOGY CENTER 2100